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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/377,795	08/20/1999	MICHAEL KARIN	P-UD-3613	8313
23535	7590	02/18/2005	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			VIVLEMORE, TRACY ANN	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/377,795	KARIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Tracy Vivlemore	1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11, 13-15 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 is/are allowed.
- 6) ☒ Claim(s) 11 and 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Information Disclosure Statement***

Applicant states in the amendment and response of January 9, 2002 that a duplicate form PTO 1449 and copies of the cited references are included with the response. However, this application has recently been scanned into IFW and these documents are not found in the scanned application. Applicant is requested to re-submit these references if they wish them to be considered.

#### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor. Inventor Zandi has indicated citizenship as US permanent residency; however, this is a residency status, not a citizenship.

#### ***Claim Rejections - 35 USC § 112 and 35 USC § 102***

The amendment of January 9, 2002 that recites the claimed nucleic acids are of human origin and removes the phrase "substantially the same" overcomes the rejection

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of record under 35 USC 112, first and second paragraphs and 35 USC 102 of claims 11 and 13-15.

***New Claim Rejections - 35 USC § 112***

Claims 11 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 11 has been amended to recite that the claimed IKK- $\gamma$  nucleic acid encodes a polypeptide "having at least 87% amino acid identity" with SEQ ID NO: 2. Claims 13-15 depend from this claim and include this limitation.

The specification at page 19, lines 22-30 contemplates embodiments wherein the IKK- $\gamma$  subunit can have an amino acid sequence having at least 35%, 45% or 55% amino acid identity to SEQ ID NO: 2 and also contemplates polypeptides having greater than 65%, 75%, 85%, 90%, 95%, 97% or 99% amino acid identity to SEQ ID NO: 2. No specific contemplation of sequences having at least 87% amino acid identity to SEQ ID NO: 2 could be found in the specification. If applicant believes such support is present in the specification, it must be pointed out with particularity in the response to this action.

Claims 11 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 11 has been amended to recite that the claimed IKK- $\gamma$  nucleic acid encodes a polypeptide "having at least 87% amino acid identity" with SEQ ID NO: 2. Claims 13-15 depend from this claim and include this limitation.

The specification at page 19, lines 22-30 contemplates embodiments wherein the IKK- $\gamma$  subunit can have an amino acid sequence having at least 35%, 45% or 55% amino acid identity to SEQ ID NO: 2 and also contemplates polypeptides having greater than 65%, 75%, 85%, 90%, 95%, 97% or 99% amino acid identity to SEQ ID NO: 2. At pages 24-27 the specification identifies methods of identifying and isolating fragments of SEQ ID NO: 2.

Nucleic acids that encode peptides having at least 87% amino acid identity to SEQ ID NO: 2 constitute a large genus of compounds that include sequences where the entire 13% of non-identity occurs in one area of the sequence, either at the end or at some portion of the sequence away from the ends. It also includes compounds where the area of non-identity is interspersed throughout the sequence in either a regular or random fashion. The polypeptide resulting from this situation would have amino acid sequences quite different from that of SEQ ID NO: 2 with no guarantee of similar function to that of SEQ ID NO: 2. The specification does not describe nor is it known in

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the art what amino acids are essential to the function of IKK- $\gamma$  such that the skilled artisan could envision which amino acids can be removed that would produce a structure that would still retain the function of being the  $\gamma$  subunit of IKK.

MPEP 2163 states in part, "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.").

#### ***Allowable Subject Matter***

The prior art searched for SEQ ID NOS: 1 and 2 reveals no prior art having at least 87% identity with SEQ ID NO: 2.

Claim 30 is allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your

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application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
February 11, 2005

SEAN MCGARRY  
PRIMARY EXAMINER

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